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FDA Acts on Food Safety Bill

Judith McGeary – May 20, 2011

The Food and Drug Administration (FDA) recently issued the first new rules under the Food Safety Modernization Act (FSMA), meeting the initial deadlines imposed by the Act.

The first rule addresses prior notice of food shipments imported from other countries. Under current law, anyone who is importing food that is subject to FDA's jurisdiction (i.e. anything except meat, poultry, or egg products) must submit prior notification to the FDA [See 21 C.F.R. § 1.278-1.279]. The FSMA added the new requirement that such notice include "any country to which the article has been refused entry" [FSMA Sec. 304]. The FDA's new rule amends the regulations accordingly.

The second rule addresses the standard for FDA to administratively detain food. Administrative detention is a limited enforcement power -- the agency can detain an article of food for no more than 30 days [See 21 C.F.R. § 1.379]. The purpose of the detention is to keep the food out of commerce while the FDA institutes a seizure or injunction action.

The FSMA lowered the standard necessary for FDA to administratively detain food, from "credible evidence" that the food "presents a threat of serious adverse health consequences of death" to "reason to believe" that the food is "adulterated or misbranded." The FDA's recent interim rule incorporates the new, lower standard.

We strongly disagree with the lowering of the standard. The practical impact of the change, however, is unclear. In the preamble to the new rule, FDA notes that, while it was given authority to administratively detain food in 2002, it has never used that authority, but instead has relied on the other enforcement tools in its arsenal [76 Fed. Reg. 25538, 25540]. But the agency also noted that, with the lower standard, it is "more likely to use administrative detention" when the food "may cause temporary or medically reversible adverse health consequences" [76 Fed. Reg. 25540]. So the FDA may begin using administrative detention, but the majority of its actions are still likely to be through other methods: immediate seizure, recalls, or by referral to State authorities (which is frequently how it attacks raw milk and raw milk cheese producers).

Both rules were issued as "interim final rules," which means that they take effect in a very short period of time. The public can submit comments on the rules, but since they both track the language of the statute precisely, there is very little chance of the agency making any changes.

It will be much more important to mobilize comments from the public when the FDA proposes rules to implement the HACCP and produce safety standard provisions of FMSA. So stay tuned for future updates and alerts.

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Hyperlinks for the PDF

278 , 279 , 379 - *Code of Federal Regulations*, Title 21, Part 1, Subpart I, section 1.278, 1.279, 1.379 = <http://ecfr.gpoaccess.gov> [Browse "Title 21 – Food and Drugs" then browse parts "1-99" to find clause.]

FSMA - Food Safety Modernization Act, codified as Public Law 111-353 = <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/html/PLAW-111publ353.htm>

25538, 25540 – "Criteria Used To Order Administrative Detention of Food for Human or Animal Consumption", *Federal Register*, Vol. 76, No.87 (Thursday, May 5, 2011), pages 25538 and 25540 = <http://www.gpo.gov/fdsys/pkg/FR-2011-05-05/pdf/2011-10953.pdf>



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